

REMARKS

The Office Action mailed September 16, 2004 has been received and the Examiner's comments carefully reviewed. Claims 1, 2, 9 and 10 have been amended. Claims 14 – 19 have been added. No new subject matter has been added. Claims 1 – 19 are currently pending. Applicants respectfully submit that the pending claims are in condition for allowance.

Claims Indicated As Allowable In Office Action

Claims 2, 3, 5, 10, 11 and 13 were indicated as allowable if rewritten in independent format including limitations of all base and intervening claims. Claims 2 and 10 are hereby so amended and submitted as allowable for the reasons given in the Office Action. Claims 3 and 5 depend from now allowable claim 2. Claims 11 and 13 depend from now allowable claim 10.

Double Patenting

Claims 1, 4, 6 – 9 and 12 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,250,307, claims 1 and 4 of U.S. Patent No. 6,546,936 and claims 1, 7 and 10 of U.S. Patent No. 6,742,524. Applicants respectfully traverse this rejection, however, to obviate the rejection, a terminal disclaimer of the term extending beyond the terms of U.S. Patent Nos. 6,250,307; 6,546,936 and 6,742,524 has been filed herewith.

Rejection of Original Independent Claims 1 and 9 Based on Schneider

In the Office Action, claims 1, 4, 6 – 9 and 12 were rejected as anticipated by Schneider (DE 4412190A1). In response to this rejection, claims 1 and 9 are amended to reflect the implant is a “solid material of pre-formed dimension”.

The text of Schneider (including claims) clearly indicate Schneider is referring to injection of flowable, injectable collagen and not a solid of preformed dimensions. Specifically, in addition to repeatedly stating the substance is “injected” (by itself

indicating a flowable substance), Schneider states the collagen “is injected successively and beginning with small doses while observing the change of the voice” (emphasis added).

The present invention pertains to a solid implant. The implant is clearly identified as a solid implant having pre-formed dimensions (i.e., not a flowable substance).

It would not be obvious to modify Schneider to be a solid. Schneider is clearly concerned with avoiding vocal effects from over-stiffening the palate. Therefore, Schneider begins injection of the flowable substance in small doses. Vocal effects are observed. If there are no adverse vocal effects, a second dose is administered and the process is repeated.

Therefore, Schneider teaches away from a solid pre-formed implant since Schneider wants to control the process with progressive doses. As a result it would not be obvious to alter Schneider to a solid implant as now recited in claims 1 and 9 since such an alteration deprives Schneider of the dose control deemed essential by Schneider.

Schneider is more similar to sclerosing therapy treatments of the soft palate. In these procedures, a fluid, flowable sclerosing agent is injected into the soft palate to create a scar. Multiple injections are commonly required after a healing period. Brietzke et al., *Injection Snoreplasty: How to Treat Snoring Without All The Pain and Expense*”, *Otolaryngology*, pp. 503 – 510 (May 2001). A problem with a fluid injection procedure such as sclerotherapy (and presumably Schneider) is that subsequent injections in the region of the previous injections is very difficult. *Id.* at p. 505.

Since claims 1 and 9 are now amended to clearly distinguish from the flowable injection of Schneider, these claims are now submitted as allowable. Dependent claims 4, 6 – 8 and 12 are submitted as allowable for the reasons given with respect to claims 1 and 9 together with the further limitations set forth in the dependent claims.

New Claims 14 – 19

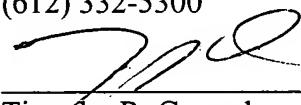
New claims 14 – 19 have been added as dependent claims corresponding to previously presented dependent claims. These claims are submitted as allowable by

reason of the allowability of their independent claims together with the additional limitations set forth in the dependent claims.

Summary

It is respectfully submitted that each of the presently pending claims (claims 1 – 19) are in condition for allowance and notification to that effect is requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby. Respectfully submitted,

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